NASA Procedural Requirements

NPR 7120.11A
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COMPLIANCE IS MANDATORY FOR NASA EMPLOYEES

NASA Health and Medical Technical Authority (HMTA) Implementation

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

P.1 Purpose

This directive describes the roles, responsibilities, and procedural requirements for implementing the HMTA to protect the health and lives of all personnel of an aircraft or a spacecraft from hazards associated with performing flight missions and associated testing and training.

P.2 Applicability

a. This directive is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This language applies to the Jet Propulsion Laboratory (JPL) (a Federally Funded Research and Development Center), other contractors, recipients of grants or cooperative agreements, and parties to other agreements only to the extent specified or referenced in the applicable contract, grant, or agreement.

b. This directive is applicable to Mission Directorates and their programs and projects performing flight activities.

c. The directive is applicable to:

(1) All NASA human space flight activities.

(2) Internationally and commercially provided space systems involving all personnel of a spacecraft, where the requirements are applicable as flowed from programs or projects, and documented in distinct separate agreements such as joint or multilateral agreements.

(3) Atmospheric flight activities involving all personnel of an aircraft.

(4) Research and Technology Development programs involving flight crews or other occupants.

(5) Specific elements of the NASA Occupational Health Program, as described herein.

d. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term “shall.” The terms “may” denotes a discretionary privilege or permission, “can” denotes statements of possibility or capability, “should” denotes a good practice and is recommended, but not required, “will” denotes expected outcome, and “are/is” denotes descriptive material.

e. In this directive, all document citations are assumed the latest version unless otherwise noted.

P.3 Authority

a. National Aeronautics and Space Act, 51 U.S.C. § 20113(a).

b. NPD 1000.0, NASA Governance and Strategic Management Handbook.

c. NPD 1000.3, The NASA Organization.

d. NPD 8900.1, Medical Operations Responsibilities in Support of Human Space Flight Programs.

e. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration.

P.4 Applicable Documents and Forms

a. NPR 1800.1, NASA Occupational Health Program Procedures.

b. NPR 7120.5, NASA Space Flight Program and Project Management Requirements.

c. NASA-STD-3001, NASA Space Flight Human System Standards.

d. NASA/SP-2014-3705, NASA Space Flight Program and Project Management Handbook.

P.5 Measurement/Verification

The CHMO will measure and verify compliance with this directive by:

a. Monitoring the development, approval, and execution of NASA Center HMTA Implementation Plans. This will include appropriate reviews by, and reporting to, the CHMO.

b. Monitoring life-cycle reviews.

c. Assessing requests for relief to applicable HMTA requirements.

P.6 Cancellation

NPR 7120.11, NASA Health and Medical Technical Authority (HMTA) Implementation, dated November 01, 2011.

Chapter 1. Introduction

1.1 HMTA Overview

As defined in NPD 1000.0, NASA Governance and Strategic Management Handbook, the NASA management system incorporates a robust system of checks and balances between the Programmatic and Institutional Authorities as an important element supporting the achievement of mission success. Figure 1 illustrates the NASA Authority Structure tracing back to the Office of the Administrator. The HMTA provides key support individuals at appropriate program and project organizational levels who have a formally delegated Technical Authority (TA) role traceable to the Administrator, and who are funded independent of the Programmatic Authority. These individuals promote open communication, serve to disposition requests for relief to established institutional requirements, provide independent oversight of programs and projects, and will collaborate with the Engineering and Safety and Mission Assurance TAs, as needed, in support of safety and mission success.

1.2 HMTA Scope

The CHMO, as described in NPD 1000.3, The NASA Organization, serves as the Agency HMTA. As the office of primary responsibility, the Office of the Chief Health and Medical Officer implements the HMTA function to ensure health, medical, and human performance policy, requirements, and standards are addressed in program and project activities to protect the health and lives of astronauts, aviation flight crews, and other occupants of flight vehicles, from hazards associated with performing the flight missions and associated testing and training (see Figure 1).

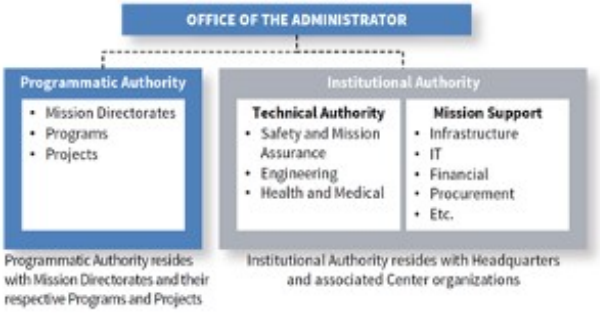

Figure 1. NASA Authority Structure

1.3 HMTA Mission

The mission of the HMTA is to both: a) prevent and mitigate adverse health and medical events and b) provide for the human performance required for successful mission execution. The HMTA is applied from program inception through operations. Specifically, the HMTA:

a. Develops and maintains NASA health, medical, and human performance policy, standards, and requirements for NASA programs and projects.

b. Dispositions requests for relief from NASA occupational, health, medical, and human performance policy, requirements, and standards. NASA-unique occupational health requirements under the scope of the HMTA are described in NPR 1800.1, NASA Occupational Health Program

Procedures.

c. Develops a disciplined systematic approach to identifying, analyzing, and controlling health, medical, and human performance risks that affect the human involved in flight.

Chapter 2. Health and Medical Technical Authority Responsibilities

2.1 Chief Health and Medical Officer (CHMO)

2.1.1 The CHMO, as the HMTA:

a. Establishes and maintains NASA health, medical, and human performance policies and standards for NASA's space flight and atmospheric flight programs and projects.

b. Concurs on the establishment of new program or project requirements.

c. Certifies program and project compliance with NASA health, medical, and human performance requirements through established Agency processes at life-cycle milestones.

d. Provides final decisional authority for any HMTA position or requests for relief associated with HMTA standards, or program or project requirements that represent change in overall risk posture for NASA; NASA programs, partners, and personnel; and the public.

e. Delegates decisional authority to the Deputy CHMO, as necessary.

f. Designates Lead HMTA Integration Centers (LHIC).

g. Concurs on Center Director appointments of NASA civil service physicians as CMOs.

h. Concurs on Center HMTA Implementation Plans.

i. Concurs on CMO appointments of CHPO as program delegates.

j. Provides training requirements for CMOs and CHPOs.

k. Engages the NASA Formal Dissent process, where necessary, and provides employees an avenue for elevating issues within the HMTA or through other single or multiple authorities (e.g., Programmatic Authority, Technical Authority) escalation paths.

2.2 Deputy CHMO

The Deputy CHMO serves as the Agency HMTA, as delegated, in the CHMO's absence.

2.3 Center Directors

The Center Directors:

a. Appoint, with CHMO concurrence, their respective Center CMO.

b. Approve, with CHMO concurrence, their respective Center's HMTA Implementation Plan.

c. Ensure necessary assets and capabilities (resources, staffing, procedures, and training) are provided to effectively implement HMTA at their Centers.

d. Ensure programs and projects residing at their Centers are in compliance with established occupational health, medical, and human performance policy, requirements, and standards through the processes specified in this directive and their Center's HMTA Implementation Plan.

2.4 Chief Medical Officers (CMO)

2.4.1 The CMO at their designated Center:

a. Develops and publishes, with approval from the Center Director and concurrence from the CHMO, their Center's HMTA Implementation Plan.

b. Exercises HMTA as described in this directive and their Center's HMTA Implementation Plan.

c. Serves, when appropriate, as a member of program or project control change, and organizational review boards.

d. Establishes appropriate HMTA interfaces with assigned programs or projects at their Centers, as described in this directive and their Centers HMTA Implementation Plan.

e. Maintains and communicates, to the CHMO or their designee, a risk status of activities at their respective Centers.

f. Maintains and communicates, to the CHMO or their designee, a forward-looking awareness of significant milestones and decisions at their respective Centers.

g. Provides the CHMO or their designee, with regular status of program issues, risks, and major milestones.

h. Maintains working communication with CMOs from other Centers to provide appropriate mutual support through local expertise, decision-making infrastructure, and medical opinion, where appropriate.

i. Exercises HMTA decisional authority at their Center, including development of HMTA program and project positions or requests for relief from HMTA standards, or program or project level requirements that are determined to be risk-neutral or have a reduction in risk.

j. Ensures all potential HMTA aeronautics and human space flight health, medical, and human performance issues identified at their Center are coordinated with their respective Center Director and the CHMO.

k. Elevates issues and requests for relief from HMTA standards or program or project level requirements that represent an increase in risk posture to NASA; NASA programs, projects, and personnel; and the public for disposition by the CHMO.

l. Engages the NASA Formal Dissent process, where necessary, and provides employees an avenue for elevating issues within the HMTA or through other single, or multiple authorities (e.g., Programmatic Authority, Technical Authority) escalation paths.

2.4.2 If the Center is designated as a LHIC, the CMO:

a. Exercises HMTA Level 2 (L2) decisional authority for the formulation of HMTA program and project positions, issue resolutions, and requests for relief from HMTA standards or program or

project level requirements associated with the LHIC.

b. Appoints, with concurrence from the CHMO, program and project CHPOs as program or project delegates.

c. Informs the program or project managers of the appointment of the program or project CHPO.

2.5 Chief Health and Performance Officers (CHPO)

2.5.1 The CHPO:

a. Serves, as delegated by the LHIC CMO, as the direct HMTA program delegate and working interface to NASA's programs and projects.

b. Exercises HMTA, within the assigned program, as described in this directive and their Center HMTA Implementation Plan.

c. Maintains and communicates a forward-looking awareness of significant milestones and decisions, as well as a comprehensive health, medical, and human performance risk posture within their respective programs, and locally coordinates an effective and timely HMTA engagement.

Chapter 3. HMTA Execution

3.1 HMTA Scope of Delegated Authority

3.1.1 The HMTA, in order to support NASA's Institutional Authority principles of independent oversight of programs and projects, delegates specific levels of decisional authority to selected individuals. All delegations are formal and traceable to the Administrator. 3.1.2 The HMTA delegated authority is comprised of: a. Level 1 (L1) - CHMO and office. b. Level 2 (L2) - Designated NASA LHIC CMO and office.

3.2 Lead HMTA Integration Centers (LHIC)

3.2.1 In order to properly align with and leverage technical resources, the HMTA is organized to take advantage of LHICs. Under such designation, the LHIC CMO serves as the HMTA L2 Decisional Authority. The LHIC CMO ensures HMTA personnel have access to qualified human system discipline expertise needed for the formulation of HMTA program and project positions, issue resolution, and adjudication of requests from relief from HMTA standards or program or project level requirements of the designated area. 3.2.2 This cross-Center collaboration promotes effective utilization of Agency expertise, avoiding duplication of resources or decisional venues used for the formulation of HMTA program and project positions, issue resolution, or adjudication of requests for relief. The NASA Centers with LHIC responsibilities, as designated by the CHMO, are: a. The Johnson Space Center for Human Space Flight activities. b. The Armstrong Flight Research Center for Aeronautics activities. c. The NASA Headquarters for all activities not delegated to individual Centers.

3.3 HMTA Delegations and Paths of Delegated Authority

3.3.1 The endpoints associated with the activities of HMTA in programs and projects are the provision for the direct management of the health and performance of flight crews in operations, and the protection of human health through the application of task-based performance standards in the integration and processing of flight vehicles. Through support for the practice of medicine, the CHMO delegates TA directly to Center CMOs as decisional integrators. Below these Center CMO's, then functions the HMTA CHPO's, who are not necessarily physicians, and serve as the direct working interface to NASA's programs and projects. This flow between physicians from L1 to L2 in HMTA is in deference to the fact that while the HMTA content is not in total medical content, there is significant direct medical practice content present in the HMTA scope, which requires decisional flow from physician to physician (See Figure 3).

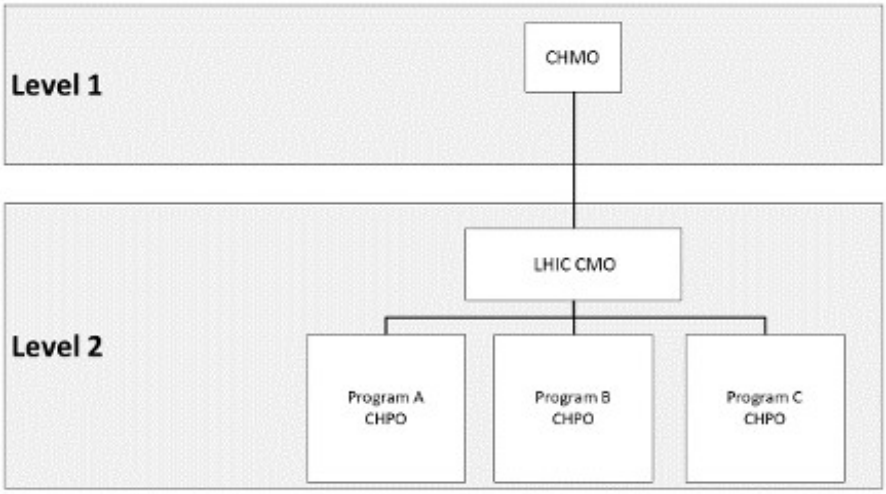

Figure 3. HMTA Delegations and Scope of Authority

3.3.2 The LHIC CMO, as delegated from the CHMO, shall make decisions that they determine to be risk-neutral or reduce overall risk.

3.3.3 The LHIC CMO shall develop and document a Risk-Based Decision-Making process for the management of HMTA issues for programs and projects under the designated area.

3.3.4 Prior to providing programs and/or projects with an HMTA decision on positions, issue resolution, and requests from relief deemed either risk-neutral or a reduction in risk, the LHIC CMO shall inform the CHMO or their designee. This "decide and inform" philosophy is vital for an effective implementation of the HMTA.

3.3.5 For issues representing an increase in risk posture as indicated by a change in their likelihood and consequences, the LHIC CMO shall investigate, evaluate, and make a recommendation to the CHMO for decision.

3.3.6 The CHPO has authority to make decisions within the scope delegated by the LHIC CMO, according to their respective HMTA Implementation Plan. Subsequent to providing programs and/or projects with HMTA decisions, CHPOs shall inform LHIC CMO, as part of the HMTA "decide and inform" philosophy.

3.4 HMTA Implementation Plans

3.4.1 The HMTA is implemented through the application of resources and processes documented in this directive and Center HMTA Implementation Plans. Center HMTA Implementation Plans describe the effective execution of HMTA at each Center with required organizational and funding separation from programs and projects. Centers shall develop their respective HMTA Implementation Plans and obtain concurrence from the CHMO.

3.4.2 The CMO shall include the following content in their respective HMTA Implementation Plan:

a. Description of organizational structure and staffing of program and project support.

b. Description of the level of delegation of HMTA to the CMO.

c. Responsibilities and scope of delegated authority of CHPOs and other interfaces with programs or

projects.

d. Description of processes for requirements management and adjudication of requests for relief.

e. Description of processes for management of formal dissents.

f. Personnel training plan.

g. If, at a designated LHIC, description of a Risk-Based Decision-Making process for management of HMTA issues.

Chapter 4. Standards and Requirements Management

4.1 HMTA Requirements Derivation

4.1.1 The LHIC CMO is delegated the authority to represent the HMTA L2 function and convey respective institutional requirements established by law, NASA policy, or other external or internal authority to program and project managers.

4.1.2 The LHIC CMO, in collaboration with other HMTA personnel, such as, CHPOs and Subject Matter Experts (SMEs) shall assess a proposed program or project architecture and their Concept of Operations for HMTA standards applicability, non-applicability, and potential HMTA standards relief (see Figure 4-1).

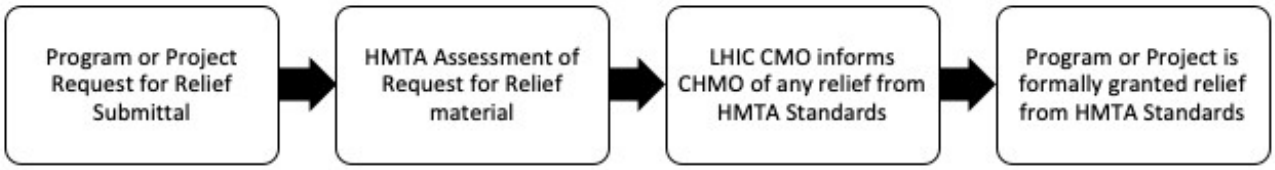

Figure 4-1. HMTA Human System Requirements Derivation

4.1.3 Following the applicability assessment, the LHIC CMO shall assist program and project managers in the development, review, and concurrence of program level human system requirements. These requirements are first instantiations of HMTA standards allocated to systems and subsystems of a proposed architecture.

4.1.4 The LHIC CMO shall maintain appropriate insight to requirements traceability to ensure program and project compliance to HMTA standards.

4.1.5 Prior to providing concurrence of baseline requirements for a program or project, the LHIC CMO shall obtain concurrence from CHMO by providing the following evidence:

a. A list of the HMTA standards identifying whether the standard is:

(1) Directly applicable as written or with modification.

(2) Not applicable.

(3) Indirectly applicable (standard will be imposed by another entity).

b. Rationale for non-applicable standards.

c. First instantiation requirements for each applicable standard.

d. Verification statements for the requirements.

4.2 Adjudication of Requests for Relief from HMTA Standards and Requirements

4.2.1 The HMTA may grant relief from standards and requirements if it is in NASA's best interest. Relief may be granted by the LHIC CMO through requesting a deviation or waiver (see Figure 4-2).

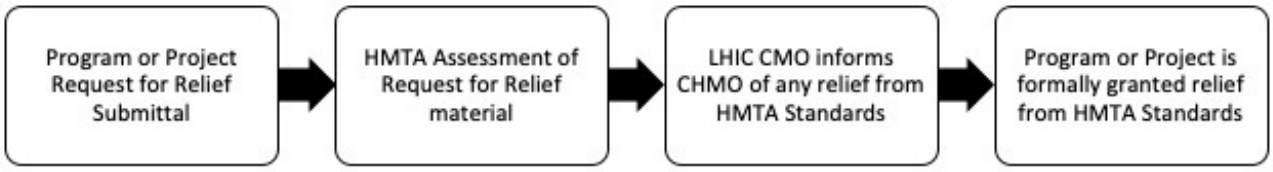

Figure 4-2. HMTA Flow for Adjudication of Requests for Relief

4.2.2 Program and project managers may submit requests for relief from HMTA standards and requirements by following the requirements tailoring process described in NPR 7120.5, NASA Space Flight Program and Project Management Requirements and the guidance given in NASA SP-2014-3705, NASA Space Flight Program and Project Management Handbook.

4.2.3 The LHIC CMO shall ensure that prior to approving or disapproving a request for relief, the following evidence is documented and considered:

a. Rationale for the waiver or deviation.

b. Risk assessment characterizing whether the request for a waiver or deviation results in a change in risk.

c. Reference to all material that provides justification supporting acceptance, including programmatic cost and schedule information.

d. List of defined risk mitigation actions/plan, including dates or development milestones for bringing program to compliance or mitigation steps closure.

e. List of all appropriate NASA organizations and SMEs involved in the review of the request for relief.

f. List of all concerns with the request that were expressed during the adjudication process.

g. Name and role of NASA management official accepting the risk and implementing requirements relief.

4.2.4 The LHIC CMO shall adjudicate the request for relief and inform the CHMO of the decision.

4.2.5 The following exceptions to the above policy for requests for relief require CHMO concurrence.

a. Changes to program requirements which increase existing risk posture.

b. Requirements representing high consequence, including:

(1) Crew survival.

(2) Life support.

(3) Abort capability.

(4) Launch escape.

(5) Crew recovery.

c. Other exceptions the CHMO has identified and communicated to the LHIC CMO.

Chapter 5. Formal Dissents

5.1 Diverse Views

5.1.1 NASA supports and promotes open discussion of issues that can improve safety and mission success throughout the Agency, including alternative and divergent views. To empower team members with the ability to provide their best input during a decision, diverse views are to be fostered and respected, without any suppression or retribution. In assessing a decision or action, an individual member has three choices: agree, disagree but be willing to fully support the decision, or disagree and raise a formal dissent. For disagreements rising to the level of importance that warrant a specific review and decision by higher-level management, NASA has formalized the Formal Dissent process.

5.1.2 A Formal Dissent is a substantive disagreement with a decision or action that is based on a sound rationale (not on unyielding opposition) that an individual judges is of sufficient importance that it warrants a specific review and decision by higher-level management, and the individual specifically requests that the dissent be recorded and resolved by the Agency Formal Dissent process. The decision on whether the issue in question is of the significance that warrants the use of the Formal Dissent process is the responsibility and personal decision of the dissenting individual.

5.2 Process for Handling Formal Dissents

5.2.1 Each program and project team member has a fundamental responsibility to express their views to the appropriate decision maker in a timely manner. Unresolved health, medical, and human performance issues within a program or project team should be quickly elevated to achieve timely resolution at the appropriate level.

5.2.2 Formal dissents adjudicated within the HMTA will be addressed using the process set forth in NPR 7120.5 and the guidance given in NASA SP-2014-3705. Formal dissents are resolved by elevation through conversations between successively higher levels of the involved.

5.2.3 The CHPO shall enable the Formal Dissent process and, if needed, the escalation of an individual formal dissent within their assigned program or project.

5.2.4 The LHIC CMO shall hear appeals of program or project-level HMTA decisions when they cannot be resolved at the program or project level.

5.2.5 The CHMO shall hear appeals of the HMTA L2 decisions at the CHMO Management Board when they cannot be resolved at the HMTA L2.

Appendix A. Definitions

Acceptance. Agreement by the appropriate NASA management official to the change in the level of risk to programs, hardware, and personnel and taking the responsibility for the potential outcome of any increase in risk.

Adjudication. The process of review, concurrence, and approval of a request for relief from an Agency-wide HMTA standard. The process includes the approval or disapproval of the request by the CHMO (or delegated approval authority) and acceptance or rejection of the change in risk and acceptance of the new risk level by the appropriate NASA management official. A request is adjudicated when all steps in the process are complete.

Aeronautics. Activities related with the study, design, and manufacturing of air flight capable machines and the techniques of operating aircraft and rockets within the atmosphere.

Approval. Decision by the HMTA that a program or project position, issue resolution, or request for relief from HMTA standards, or program or project level requirement may be implemented after the appropriate NASA management official accepts the risk.

Chief Health and Performance Officer (CHPO). Personnel delegated by the LHIC CMO to serve as the direct HMTA working interface with programs or projects.

Chief Medical Officer (CMO). A physician assigned to designated NASA Centers by the CHMO who serves as the delegated HMTA for that Center.

Concurrence. A documented agreement by a management official that a proposed course of action associated with a program or project position, issue resolution, request for relief from HMTA standards, or program or project level requirements is acceptable.

Decide and Inform. Philosophy used by HMTA that allows lower level TAs to make independent decisions that are risk-neutral or reduce risk and also keep the next higher level of HMTA informed of those decisions.

Delegation. The official process for assigning TA to a named individual and communication of that delegation to the appropriate community.

Deviation. A documented authorization releasing a program or project from meeting a requirement before the requirement is put under configuration control at the level the requirement will be implemented.

Formal Dissent. A disagreement with a decision or action that is based on a sound rationale (not on unyielding opposition) that an individual judges is of sufficient importance that it warrants a specific review and decision by higher-level management, and the individual specifically requests that the dissent be recorded and resolved by the Formal Dissent process.

First Instantiation. The first representation of a standard in program or project-level requirements.

Health. Individual/cohort physical and psychological well-being.

Human Performance. The capabilities and needs of the human defined by physical, cognitive, and psychological traits that are applied to the design of vehicles and operational tasks to achieve

mission success as captured in HMTA Standards.

Human System. The Human's capabilities and needs when considered in a systematic fashion programmatically on an equal footing to other systems in a given architecture.

Human System Disciplines. The family of human-related clinical, technical, and scientific disciplines closely associated with the performance capabilities and needs of the human (e.g. clinical medicine, nutrition, toxicology, physical performance, cognitive abilities, human factors, microbiology, and health physics) as captured in NASA STD 3001, NASA Space Flight Human System Standards.

Medical. The prevention, diagnosis, and treatment of acute or chronic illness or injury.

Relief. A waiver, deviation, or request for determination of non-applicability to modify or eliminate a stated standard and usually not meet the full intent and letter of the standard as stated.

Risk-Based Decision-Making. The process that organizes information about the possibility of various outcomes into an orderly structure that helps decision makers make better informed management choices.

Risk Neutral. Outcomes of programmatic decisions, proposed implementation, pursuit of standards/requirements deviations, and/or waivers that do not change the overall likelihood and consequence of the health, medical, and human performance risks baselined by CHMO for a particular program or project.

Subject Matter Expert (SME). Person recognized as an expert in the technical area under review.

Tailoring. The process used to adjust or seek relief from a prescribed requirement to accommodate the needs of a specific task or activity (e.g., program or project). If revised requirement meets/exceeds the parent standard, and has no increase in risk from the original requirement, then it may be accepted/implemented by the appropriate delegated authority; otherwise, a waiver/deviation may be required.

Technical Authority (TA). A part of NASA's checks and balances system that provide independent oversight of programs and projects in support of safety and mission success through the selection of individuals at delegated levels of authority. TA delegations are formal and traceable to the Administrator. Individuals with TA are funded independently of a program or project.

Technical Standards. NASA documents that contain common and repeated use of rules, conditions, guidelines, or characteristics for products, or related processes, production methods and related management system practices.

Traceability. The process of mapping original standards and requirements to implementing requirements.

Waiver. A documented authorization releasing a program or project from meeting a requirement after the requirement is put under configuration control at the level the requirement will be implemented.

Appendix B. Acronyms

CHMO	Chief Health and Medical Officer
CHPO	Chief Health and Performance Officer
CMO	Chief Medical Officer
HMTA	Health and Medical Technical Authority
JPL	Jet Propulsion Laboratory
L1	Level 1
L2	Level 2
LHIC	Lead HMTA Integration Center
SME	Subject Matter Expert
TA	Technical Authority

Appendix C. References

C.1 NPD 1800.2, NASA Occupational Health Program.

C.2 NPD 7120.4, NASA Engineering and Program/Project Management Policy.

C.3 NPR 8000.4, Agency Risk Management Procedural Requirements.